REMARKS

I. STATUS OF THE APPLICATION:

Claims 1-2, 8, 11-19, 23, 25, 28-51 and 53-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.P.A. Pub. No. US2003/0208454 ("Rienhoff *et al.*") in view of U.S.P.A. Pub. No. US2003/0110058 ("Fagan *et al.*"), and further in view of U.S.P.A. Pub. No. US2003/0082865 ("Bianco"), and further in view of U.S. Patent No. 7,080,098 ("Smirniotopoulos *et al.*").

Independent claim 18 has been amended to correct informalities pointed out by the Examiner. None of the other claims have been amended. Claims 3-7, 9-10, 20-22, 24, 26-27 and 52 were previously cancelled. Claims 1-2, 8, 11-19, 23, 25, 28-51 and 53-57 are currently pending.

Claims 1, 18, 34, 35, 36, 37, 47, 48, and 56 are independent claims. Claims 1, 34, 35, 36, 37, 47, and 56 are directed to a system for clinical research data management. Claim 18 and 48 are directed to a method for clinical research data management.

II. CLAIM OBJECTIONS:

As mentioned, claims 18 has been amended to correct informalities pointed out by the Examiner. Applicants thank the Examiner for careful review of the claims.

III. CLAIM REJECTIONS UNDER 35 U.S.C. 103:

As mentioned, Claims 1-2, 8, 11-19, 23, 25, 28-51 and 53-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rienhoff *et al.* in view of Fagan *et al.*, in view of Bianco, and further in view of Smirniotopoulos *et al.* Applicants respectfully traverse this rejection for the reasons explained below.

A. None Of The Cited References Teach A System Or Method Operable To "Limit" Or Impose "Restrictions" On Communications Between Users

Independent claims 1, 18, 34, 35, 36, 37, 47, and 56 all require an element or step operative to "limit communication of electronic messages between users ... having a specific role in connection with a specific study." Independent claim 48 includes a very similar limitation: "imposing role-based restrictions on user access to the clinical study data and on communications between users having a specific role in connection with a specific study."

As explained in the Request for Continued Examination ("RCE") filed on April 17, 2007, none of the cited references impose any "**limit**" or "**restrictions**" that would preclude any particular users from

sending or receiving messages based on roles in connection with particular studies. *See* RCE dated April 17, 2007, pp. 13 and 14.

In response to the remarks presented in the RCE dated April 17, 2007, the present Office Action suggests that Rienhoff teaches the claimed "limit" on communications where Rienhoff states:

> Additionally, the **web site may provide users with information** regarding ongoing medical studies, drug studies, genetic studies, etc., and may provide information on how a user can participate in such studies. The web site may provide such information via general **postings viewable by all users**, or provide **information to selected users**. For example, the information could be **directed to individual users via email** or **web pages viewable to groups of users who have registered** with the web site. In one embodiment, the web site may provide users the ability to volunteer for such studies via the web site. In another embodiment, certain **users may be selected for invitations based on phenotypic and/or genotypic information they previously submitted**.

Office Action, p. 5 citing Rienhoff, ¶ 47 (emphasis added).

As indicated above, Rienhoff teaches a system that sends email to selected users. As explained in the remarks presented in the RCE dated April 17, 2007, the "users" in Reinhoff are not the same as the "users" recited in the pending claims.[1] Regardless, Rienhoff does not suggest imposing any "**limit**" or "**restrictions**" on sending messages between any users, as recited in the independent claims. There is an important difference between merely facilitating communications to selected users (as taught by Reinhoff) versus imposing a "**limit**" or "**restrictions**" on messages sent between selected users. As explained in the specification of the present application, the advantage of limiting communications in the claimed manner is that it provides a secure environment.

> The system advantageously provides a **secure environment** within which users can communicate about a given study. **No messages can be sent or received** in connection with a given study unless the author and recipient(s) have been assigned the proper role in connection with the study.

Specification, ¶ 182 (emphasis added).

The claimed "limit [on] communication of electronic messages *between* users" not only imposes a "limit" on which users may *receive* messages pertaining to a certain study, but also on which users can *send* messages pertaining to a certain study. Reinhoff does not even talk about the ability of any users to send messages or post information. Actually, Reinhoff states that "***the web site*** may provide users with

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[1] Applicants note that the meaning of the word "user" in Rienhoff is not the same as the meaning of that term in the claims of the present invention. In Rienhoff, the word "user" means an individual who provides health information to the system. The word "user" in the claims refers to persons, such as medical personnel, who use the system for clinical research.

information." Rienhoff, ¶ 47 (emphasis added). Based on this comment, it is not even clear that the system taught by Reinhoff even allows communications between users at all. In contrast, the present invention provides for communication of electronic messages between different users within the same system.

Even if Reinhoff taught communication between users (which it does not), Reinhoff certainly describes no "limit" on communications between users. Therefore, the system taught by Reinhoff would actually facilitate an unsecure environment, which is antithetical to the system and method claimed in the present invention. As such, Reinhoff not only fails to teach the claimed "limit" and "restrictions," but it actually teaches away from these important features.

The claimed "limit" (or "restrictions") serve to prevent the sending of messages (in connection with a given study) to or from any user who has not been assigned a role entitling him to such privileges. This feature, taken together with the claimed "roles," allows for creating a secure communications environment in connection with a certain data study. This security feature is important because it protects the integrity of the data study by preventing unauthorized communications in connection with the study.

In conclusion, none of the cited references teaches a "limit" (or "restrictions") on communication between users as recited in each of the independent claims 1, 18, 34, 35, 36, 37, 47-48 and 56. Because none of the cited references teach these limitations, these claims are patentable over the cited references. All of the other pending claims depend from the patentable independent claims, rendering the dependent claims patentable also.

B. None Of The Cited References Teach A System Or Method Wherein A Role Based Security Scheme Is Used To Limit Communications Between Users In Connection With a Specific Study

As explained above, none of the cited references teach a "limit" (or "restrictions") on communication between users. However, even if any of the cited references did teach this element (which they do not), none of the cited references teach assignment of ***"roles"*** for the purpose of limiting communication of electronic messages between users "having a specific role in connection with a specific study."

The present Office Action concedes that Rienhoff, Fagan and Bianco do not teach role-based access control. Office Action, p. 6. However, the rejections of all of the pending claims rely on Smirniotopoulos for a teaching of a role-based access control scheme. *See, e.g.,* Office Action, p. 6. It is true that Smirniotopoulos teaches a generalized role-based access control scheme, but it fails to teach the specific "roles" that are employed to significant advantage in the claimed invention. For example, Smirniotopoulos fails to teach the "data study administrator role" recited in independent claims 1, 18, 35,

36, 37, and 47-48. More importantly, Smirniotopoulos fails to teach use of a role-based access control scheme to limit communications between users.

Smirniotopoulos teaches conventional use of a role-based access control scheme to protect data stored in a database, but it does not teach use of a role-based access control scheme to limit communications between users. The five "roles" contemplated by Smirniotopoulos (*i.e.,* author, reviewer, guest, editor and system administrator) are all used to assign privileges associated with authoring, editing and viewing files. Smirniotopoulos does not teach, hint or suggest an element or step operative to "limit communication of electronic messages between users ... having a specific role in connection with a specific study" as recited in independent claims 1, 18, 34, 35, 36, 37, 47 and 56. Also, Smirniotopoulos does not teach "imposing role-based restrictions on user access to the clinical study data and on communications between users having a specific role in connection with a specific study" as required by independent claim 48.

Employing a role-based access control scheme to assign privileges associated with authoring, editing and viewing files (as taught by Smirniotopoulos) does not teach or suggest use of a role-based access control scheme to impose a limits on "communication of electronic messages between users ... having a specific role in connection with a specific study." A system for assigning privileges allowing a user to author or edit a data file (as taught by Smirniotopoulos) is not the same as according a privilege allowing a user to send or receive electronic messages in connection with a specific study. For one thing, controlling access to data files is simply not the same as imposing a limit on "communication of electronic messages." While the role-based access control scheme taught by Smirniotopoulos provides security concerning authoring and editing data files, it does not even contemplate the need for a secure environment relating to communication of electronic messages in connection with a specific study.

In the present invention, there is an important synergy between many of the claimed elements. For example, the "limit" on communications and the use of "roles" are combined to allow system administrators (*i.e.,* the "users" assigned the "data study administrator role" and the "system administrator role") to control the parameters of a secure communication environment by defining exactly which users can send and receive certain messages. *See* Specification, ¶ 182.

In conclusion, none of the cited references teach the assignment of ***"roles"*** for the purpose of limiting communication of electronic messages between users "having a specific role in connection with a specific study" as recited in each of the independent claims 1, 18, 34, 35, 36, 37, 47-48 and 56. Because none of the cited references teach these limitations, the independent claims are patentable over the cited

references. All of the other pending claims depend from patentable claims 1, 18, 34, 35, 36, 37, 47-48 and 56, rendering them patentable also.

C. Even If The Elements Taught By Reinhoff, Smirniotopoulos And The Other Cited References Can Be Combined, The Combined Result Does Not Lead To The Claimed Invention

Reinhoff And Smirniotopoulos, taken either individually or collectively, do not teach an element or step operative to "limit communication of electronic messages between users ... having a specific role in connection with a specific study," as recited in independent claims 1, 18, 34, 35, 36, 37, 47 and 56. The present Office Action improperly relies on Reinhoff for a teaching of imposing a "limit" on communications of electronic messages between users, and also improperly relies on Smirniotopoulos for a teaching the assigning of "roles" to limit communications. Office Action, pp. 5-6. As explained above, Reinhoff does not teach any "limit" or "restrictions" on communication of electronic messages between users. While Smirniotopoulos teaches application of a role based access scheme to control authoring and editing of data files, it does not contemplate use of a role based access scheme to impose a "limit" or "restrictions" on communications of electronic messages "between users having a specific role in connection with a specific study."

In its recent opinion on the issue of obviousness, the Supreme Court stated:

> A court must ask whether the improvement is more than the predictable use of prior-art elements according to their **established functions.**

KSR Int'l Co. v. Teleflex. Inc., No 04-1350 (U.S. Apr. 30, 2007), slip op. at 14 (emphasis added).

The "established function" of a role-based access scheme, as described by Smirniotopoulos, is to prevent authoring and editing of data files by unauthorized personnel. However, in the present invention, a role based access scheme is not used for this established function, but rather to impose a "limit" or "restrictions" on communications of electronic messages "between users having a specific role in connection with a specific study." This limiting of communications protects the integrity of the study, not by preventing unauthorized changes to data files (as taught by Smirniotopoulos), but by preventing unauthorized *communications* in connection with the study. The present Office Action presents no apparent reason for a person of ordinary skill in the art to apply a role based access scheme for this explicitly claimed function, and the cited references certainly do not teach this element. Applicants submit that the claimed invention constitutes a useful innovation that is far more than the predictable use of prior-art elements according to their established functions, and that the pending claims are therefore non-obvious over the cited references. The advantages of the claimed invention have already been described.

D. The Cited References Fail To Teach Numerous Claim Elements Recited In The Dependent Claims

Regarding claims 2 and 19, the Office Action has cited paragraph 44 of Rienhoff as the basis of the rejection. However, the events referred to in claim 2 are not those in the cited portion of Rienhoff. The events in claim 2 are contacts with medical personnel. Such events include an initial visit, surgery and follow up visits. Applicants' Specification, page 22. The events referred to in Rienhoff refer to on-line events to gain the trust of a subject. Therefore, the cited portion of Rienhoff does not support the rejection.

Regarding claims 8 and 25, the Office Action has cited paragraph 41 of Rienhoff as the basis of the rejection. The cited portion only describes that users of the web site may control the access rights to the information they submit to the web site in order to obtain or maintain the trust of the user. There is no mention of roles defining access rights at the dataset definition level or data item level. Therefore, the cited portion of Rienhoff does not support the rejection.

Regarding claims 11 and 28, the Office Action has cited paragraph 41 of Rienhoff as the basis of the rejection. However, the cited portion of Rienhoff does not describe that a role defines a user's capability to view privacy data. There is no mention of roles in the cited portion. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 17, the Office Action has cited paragraph 101 of Rienhoff as the basis of the rejection. However, the encryption referred to in the reference is not encryption of the data in the database, as recited in the claim. The cited portion of the reference only refers to encryption of data in a consent form obtained from a web site. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 23, the Office Action has cited paragraph 80 of Rienhoff as the basis of the rejection. However, the cited portion of the reference says nothing about roles and confuses the meaning of users in the reference with the meaning of users in the claims. See footnote 1. Therefore, the cited portion of the reference does not support the rejection.

Regarding claims 38 and 49, the Office Action has cited paragraph 46 of Rienhoff as the basis of the rejection. However, the users referred to in the reference are not the users of the system referred to in claim 37. See footnote 1. Therefore, the cited portion of the reference does not support the rejections.

Regarding claims 39-43, the Office Action has cited paragraph 129 of Rienhoff as the basis of the rejections. However, the cited portion of the reference says nothing about database tables, especially

database tables that have fields associated with roles and events. Therefore, the cited portion of the reference does not support the rejections.

Regarding claim 44, the Office Action has cited paragraph 107 of Rienhoff as the basis of the rejection. However, the cited portion of the reference only refers to the types of samples that can be collected from a subject. The cited portion of the reference says nothing about the recording of an event in the database when an interaction with a study subject occurs. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 45, the Office Action has cited paragraph 69 of Rienhoff as the basis of the rejection. The cited portion of the reference describes types of queries on a questionnaire. The cited portion does not describe events as the term is used in the present invention, wherein events such as an initial visit, a surgery or a follow-up visit or treatment are stored in a table in the database. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 46, the Office Action has cited paragraph 108 of Rienhoff as the basis of the rejection. Paragraph 108 describes the process of analyzing samples. It does not state that the process is defined as an event which is recorded as such in the tables of the database. Furthermore, the cited portion does not describe scheduled or unscheduled events or events that are predefined or any status associated with an event for tracking purposes. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 49, the Office Action has cited paragraph 46 of Rienhoff as the basis of this rejection. However, paragraph 46 says nothing about maintaining an audit trail that records users' access information. Again the users in Rienhoff are being confused with the users of the present invention. See footnote 1. Claim 49 refers to the step of imposing role-based restrictions on user access. The cited portion of the reference says nothing about role-based restrictions on user access and nothing about whether this access information is recorded in an audit trail. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 50, the Office Action has cited paragraph 41 of Rienhoff as the basis of the rejection. Paragraph 41 does not address the user's access information as that term is used in the claims. Again, the Office Action confuses the meaning of the term user in Rienhoff with that of the present invention. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 51, the cited portion of the reference, paragraph 41 of Rienhoff, says nothing about whether the level of access is a dataset level or dataset item. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 53, the Office Action has cited paragraph 46 of Rienhoff as the basis of the rejection. However, paragraph 46 says nothing about how a capability can be mapped to a functional portion of the system. See Applicants' specification at page 30. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 54, the cited portion of the reference, paragraph 47 of Rienhoff, says nothing about the functional portions listed in the claim. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 55, the cited portion of the reference, paragraph 48, says nothing about deploying functional elements of the system for a clinical study and nothing about the functional elements of the system listed in claim 55. Therefore, the cited portion of the reference does not support the rejection.

IV. CONCLUSION REGARDING CLAIM REJECTIONS UNDER 35 U.S.C. 103:

Although the foregoing examples are not exhaustive, it is clear from these examples that the cited references do not support a prima facie case of obviousness of pending claims 1-2, 8, 11-19, 23, 25, 28-51 and 53-57. Because the above-discussed claim elements appearing in the independent claims are neither taught nor suggested by the cited references, all of the pending claims are allowable over the cited references. Accordingly, Applicants respectfully request reconsideration and withdrawal of the claim rejections.

V. CONCLUSION

No fees beyond are believed to be due in connection with this Amendment. However, the Director is authorized to charge any additional fees that may required, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 **(Order No. 369526-101 (346323))**.

Respectfully submitted,

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